

(2) For purposes of determining quality factors related to distribution and storage, a collection of primary containers or units transported, stored, or held under conditions as nearly uniform as possible.

(b) A *sample* consists of 10 subsamples (consumer units), taken one from each of 10 different randomly chosen shipping cases to be representative of a given lot, unless otherwise specified in a specific quality standard in this part.

(c) An *analytical unit* is the portion(s) of food taken from a subsample of a sample for the purpose of analysis.

[42 FR 14325, Mar. 15, 1977]

**§ 103.5 General principles.**

(a) The quality of a food depends upon numerous characteristics including but not limited to the levels of microorganisms and such physical factors as turbidity, color, flavor, and odor. Such characteristics are indicative of the quality of the raw materials and ingredients, the degree of quality control used in manufacture, processing, and packing, and the conditions of distribution and storage. The diversity of raw materials, food processing, and distribution practices, as well as the variation in quality factors important to consumers, requires that individual standards of quality be established for different types of food.

(b)(1) The label of a food that fails to meet the requirements of an applicable standard of quality promulgated pursuant to this part shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement, "Below Standard in Quality———", the blank to be filled in with whichever of the following are applicable:

- (i) "Contains Excessive Bacteria".
- (ii) "Excessively Turbid".
- (iii) "Abnormal Color".

(iv) The phrase specified in the applicable standard of quality to describe any other quality deviation.

(2) The statement of substandard quality shall appear on the principal display panel or panels and shall immediately and conspicuously precede or follow, without intervening written,

printed or graphic matter, the name of the food.

(c) Product descriptions included in a standard of quality promulgated pursuant to this part are intended only to designate the class of foods to which the standards apply, and are not standards of identity for the products involved. Should a standard of identity later be established for any of these foods, the standard of quality will be recodified to appear in the same part of the regulations.

(d) The food characteristics included in a standard of quality published in this part relate only to the quality of the food and not to compliance with any of the adulteration provision of section 402 of the act. Compliance with a standard of quality promulgated pursuant to this part does not excuse failure to observe either the requirement of section 402(a)(4) of the act that food may not be prepared, packed, or held under insanitary conditions, or the provisions of parts 110 and 129 of this chapter requiring that food manufacturers must observe current food manufacturing practices. For example, evidence obtained through factory inspection indicating such a violation renders the food unlawful, even though the food contains levels of microorganisms lower than those prescribed by an applicable standard.

(e) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may establish, amend, or repeal, under subpart B of this part, a regulation prescribing a standard of quality for a food pursuant to part 10 of this chapter.

[42 FR 14325, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977; 44 FR 12172, Mar. 6, 1979]

**Subpart B—Standards of Quality**

**§ 103.35 Bottled water.**

(a) *Definitions.* (1) *Bottled water* is defined as water that is sealed in bottles or other containers and intended for human consumption. Bottled water does not include mineral water or any type of soft drink commonly known as soda water, which is made by absorbing carbon dioxide in potable water.